

Implementation of warfarin to direct oral anticoagulant conversion initiative in pharmacist-run anticoagulation clinics during COVID-19 pandemic

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Abstract

Due to community transmission of coronavirus disease 2019 (COVID-19), social distancing and stay-at-home orders were implemented statewide in an effort to limit the spread of disease. This posed unique challenges for patients on medications requiring close and continued monitoring by clinic staff, such as anticoagulation clinics. Thus, innovative measures were implemented at Cleveland Clinic Health System (CCHS) to maintain the health and care of ambulatory patients. An initiative to evaluate patients for warfarin to direct oral anticoagulants (DOAC) conversion was used in the pharmacist-run anticoagulation clinics. This article describes how patients were screened for eligibility, the education to pharmacists, the utilization of student learners in the process, and the workflow for provider notification of conversion. Follow up monitoring, challenges encountered, and future directions are also described.

KEYWORDS

ambulatory care, anticoagulation, COVID-19, DOAC, pharmacy services, warfarin

1 | INTRODUCTION

On March 11th, 2020, the World Health Organization (WHO) declared the novel coronavirus disease 2019 (COVID-19) a global pandemic.¹ This declaration resulted in a need to limit patient's community and healthcare exposure to the virus. With the onset of COVID-19, anticoagulation clinics across the United States scrambled to adapt. Several outpatient services were halted or transitioned to virtual platforms. However, this was not an option for pharmacist-run anticoagulation clinics at Cleveland Clinic Health System (CCHS), which primarily relied on face-to-face visits to obtain capillary blood samples to measure anticoagulation control of warfarin. The Anticoagulation Forum, an organization representing anticoagulant service providers, developed recommendations for the management of anticoagulation during the pandemic. Their guidance advised clinics to create a standardized protocol to review and identify patients eligible for warfarin to direct oral anticoagulants (DOAC) transition in order to limit potential risk of COVID-19 exposure.² This article describes the approach taken to create and implement a warfarin to DOAC

conversion initiative in pharmacist-run anticoagulation clinics at a large academic medical center.

2 | BACKGROUND

CCHS pharmacist-run anticoagulation clinics are staffed by over 20 pharmacists across 11 locations in the northeast Ohio area. Before COVID-19, CCHS Pharmacy Anticoagulation Clinic (PAC) were primarily focused on face-to-face point-of-care (POC) visits for warfarin management. Telemanagement through laboratory monitoring and home international normalized ratio (INR) testing was performed in a limited capacity. At the onset of the pandemic, PAC took a multi-pronged approach to limit patient's health care exposure including implementing drive thru INR services and extending time until next POC visit. In addition, there was interest in developing a warfarin to DOAC conversion initiative, which was a new service for the clinics. A focus group met three weeks after the global pandemic was declared to assess needs, brainstorm ideas, and implement changes in

response to the pandemic. In the state of Ohio, clinical pharmacists practice under a collaborative practice agreement to manage drug therapy. The PAC consult includes warfarin, parenteral agents, and DOACs. Before COVID-19, DOAC management services were considered but never fully developed.

Within the last decade, there has been discussion on the current state of warfarin clinics and the opportunity to expand anticoagulation management services to include DOAC management.³ As DOAC management became more common, several organizations have published outcomes of pharmacist involvement in various DOAC management models.^{4,5} To date, there are few publications describing anticoagulation management during the pandemic. Kow and colleagues provided an algorithm to use during COVID-19 which suggests re-evaluation of anticoagulation need, followed by consideration for change to DOAC, change to parenteral agent, or self-monitoring of INRs to limit health care exposure.⁶ It includes clinical therapeutics on how to approach such conversions, but does not elaborate on the actual clinic implementation and associated challenges of utilizing this workflow.

2.1 | Identification of eligible patients

Patients were identified for potential warfarin to DOAC conversion through multiple methods. The first method was during face-to-face POC INR monitoring visits, in which the pharmacist reviewed eligibility for DOAC conversion. During an in-person visit, the pharmacists could utilize the patient's visit time to discuss the reasons for the recommendation of DOAC conversion and answer any questions the patients had, such as the advantages and disadvantages of DOAC therapy compared with warfarin. The second method was through the PAC call center staff. Due to statewide stay-at-home orders, the PAC call center had high call volumes with patients requesting to cancel or reschedule face-to-face visits due to concerns of possible exposure. If the call was conducted by or routed to a pharmacist for review, further evaluation of warfarin to DOAC conversion was considered. The third method was through an effort to obtain a list of all patients within the health system attributed to PAC. The intent was to prospectively review each patient chart and contact DOAC eligible patients regarding warfarin to DOAC conversion. PAC contacted information technology to assist in downloading this patient list from the electronic health record (EHR). When a patient had a consult placed to PAC, the intake staff manually added this patient on a patient list within the EHR; if the office staff was notified of patient discharge (such as patient stopping warfarin or repeated no show visits) the patient was manually removed from the list. There were limitations to this list given the manual addition and deletion of patients. Student pharmacists available for remote work within the health system were utilized to assist in screening the patient list, as described in a later section. After removing patients screened and documented as deceased, the list contained 4545 patients. The list was subdivided by PAC geographic location and secured on a local network drive.

Project leads were identified within the PAC team. Leads created a "DOAC conversion checklist" which outlined eligibility criteria for DOACs (Table 1).⁷ Patients were deemed appropriate for conversion if all the questions in the checklist were answered "YES." The purpose of this checklist was to prevent inappropriate recommendations, such as when a patient had a precaution or a contraindication DOAC use.

2.2 | Process for patient conversion

Once the patients were identified through one of the methods above, the option of conversion was discussed with the patient. Shared decision-making was used to engage the patient in discussion. Patients were educated on risks versus benefits of the anticoagulants, possible differences in cost, and key counseling points. Pharmacists also discussed current guideline recommendations for atrial fibrillation and venous thromboembolism, which list DOACs as first-line therapy over warfarin.⁸⁻¹⁰ Affordability was a major driver for most patients, as DOACs are not available in the United States through generic formulations and often result in high copayments on many insurance plans.

If a patient met eligibility criteria for conversion and discussed the option with a pharmacist, the pharmacist documented the outcome in the EHR. A standardized template was created that outlined the "DOAC conversion checklist" so that other providers could view the pharmacist's assessment in the EHR (Figure 1). A free text area was included for pharmacists to enter any additional patient-specific factors or considerations. In early stages of this initiative, medication orders were pended to the referring provider for review and approval. While DOACs are included in the PAC consult agreement, physicians were not accustomed to pharmacists independently making the decision to convert a patient from warfarin to DOAC. As experience was gained throughout this initiative, PAC solicited input from CCHS providers who expressed interest in pharmacists independently initiating the warfarin to DOAC conversion under the existing consult agreement. Pharmacists contacted the patient to discuss the next steps and to facilitate safe conversion. Patients were scheduled for telephonic follow-up with the PAC team one month from conversion date, and were added to a shared EHR list for tracking purposes. Physicians were informed of patients who transitioned from warfarin to DOAC via the EHR.

2.3 | Education to pharmacists

Project leads developed education to pharmacists on this topic. A step-by-step guidance document on how to pursue conversions was created that included the "DOAC conversion checklist" as mentioned above (Table 1).⁷ This checklist included: indication for anticoagulation, renal and hepatic function, drug-drug interactions, body weight, and adherence. The step-by-step document also described differing insurance types and expected coverage and copayments. A sample script for introducing DOACs and providing education to the

TABLE 1 DOAC Conversion Checklist⁷

Patient characteristic	Definition	YES to ALL = DOAC candidate	NO to ANY = do NOT suggest conversion
Approved indication	YES if: Atrial fibrillation (non-valvular) ^a , Venous thromboembolism, prevention of cardiovascular events (CAD, PAD) NO if: Mechanical valve replacement, moderate to severe mitral stenosis, antiphospholipid syndrome Caution in indications outside of those listed above (select examples): <ul style="list-style-type: none"> • Left ventricular thrombus • Treatment of cancer-related VTE • Chronic thromboembolic pulmonary hypertension • Thrombosis in unusual sites (renal/splenic/mesenteric/portal/cerebral vein) 	Yes	No Further clinical review needed or shared decision making with provider
Adequate renal function	CrCl >30 mL/min (using actual body weight), not on dialysis ^b	Yes	No
Adequate hepatic function	Mild hepatic impairment or no hepatic impairment	Yes	No
Without significant drug-drug interaction (DDI) ^c	Review medication list and run interaction check (watch out for inducers/inhibitors of P-gp and CYP3A4 such as rifampin, ketoconazole, dronedarone, itraconazole)	Yes	No
Acceptable body weight	Weight > 50 kg and < 120 kg (BMI < 40 kg/m ²)	Yes	No
Patient adherent to medication	Discuss with the patient (may also do quick chart review regarding adherence to visits for point-of-care INR, review problem list for item suggesting issues with adherence)	Yes	No

Other factors to consider: *Breastfeeding, pregnant patient*—should not be on DOAC (yet also NOT be on warfarin, low likelihood of encountering this patient type). *Recent GI bleed (GIB)*—consider warfarin or apixaban (dabigatran and rivaroxaban on Beer's list for risk of GIB in elderly). *History of bariatric surgery*—consider keeping patient on warfarin due to unknown absorption and more limited data (could consider shared decision making with patient/provider). *Previous DOAC use*—review allergy/intolerance list, review medication list and filter for apixaban/rivaroxaban/dabigatran/edoxaban; if DOAC trialed and failed in the past (intolerance, side effect, thrombosis while on DOAC), likely should NOT transition back to DOAC.

^aSee p.11 Michigan Anticoagulation Quality Improvement Initiative (MAQI) toolkit for more guidance on non-valvular atrial fibrillation.

^bApixaban has limited data in dialysis patients, avoid use for purposes of this conversion.

^cSee p. 58 to 59 MAQI toolkit for more guidance on DDIs with DOAC.

Abbreviations: BMI, body mass index; CAD, coronary artery disease; CrCl, creatinine clearance; DDIs, drug-drug interactions; DOAC, direct oral anticoagulant; INR, international normalized ratio; PAD, peripheral artery disease; P-gp, P-glycoprotein.

patient was included for pharmacists to utilize (Table 2). The checklist and step-by-step document were shared with the pharmacist team via email and through two live (virtual) one hour training sessions. Project leads remained available for questions on patient-specific cases. Due to an influx of questions by the pharmacists to the team leads, a frequently asked questions document was created and available on a shared drive for recurring DOAC questions, such as consideration for thrombophilia and off-label indications. If pharmacists had uncertainty regarding a patient's "eligibility criteria," pharmacists were encouraged to enter encounters into the EHR and route to referring provider and or specialist provider (if applicable) for their input.

2.4 | Utilization of learners

Advanced Pharmacy Practice Experience (APPE) students who were on rotation at CCHS were displaced from scheduled rotations during COVID to maintain social distancing. Health system administrators reassigned rotations so that learners could support the anticoagulation conversion initiative starting mid-April 2020. A total of approximately 30 students were assigned to this initiative through the end of May 2020. APPE students continued to report on-site due to limitations with access to patient-protected information off-site. There was a postgraduate year 1 (PGY1) pharmacy resident on

FIGURE 1 Standardized template for DOAC conversion documentation in EHR. COVID-19, novel coronavirus disease 2019; CrCl, creatinine clearance; DOAC, direct oral anticoagulant

Cleveland Clinic Ambulatory Pharmacy
Anticoagulation Clinic

Patient identified for potential conversion from warfarin to DOAC in response to COVID-19 outbreak.

Chart review:

List indication(s) for anticoagulation	
Approved indication for DOAC	Yes/No
Adequate renal function	Yes/No
Adequate hepatic function	Yes/No
Without significant drug-drug interaction	Yes/No
Acceptable body weight	Yes/No
Patient adherent to medication	Yes/No
List additional considerations/factors	

If **YES** to **ALL** = patient is DOAC candidate

Estimated CrCl: _____ mL/min

Assessment:

- Based on chart review, patient is a DOAC candidate: Yes/No
- Contacted patient, agreeable to DOAC: Yes/No

Plan:

- Suggested DOAC: _____
- Suggested dosing: _____
- Encounter routed to referring provider for review

Pharmacist name: _____

Pharmacy Anticoagulation Clinic
Phone:
Pager:

rotation with the anticoagulation manager who assisted in organizing student assignments and leading virtual student training. Students were trained on how to review charts using the “DOAC conversion checklist” and determine if the patients may be DOAC eligible. They then updated patient lists on the shared drive and followed instructions on how to add appointment notes for eligible patients. These appointment notes were visible to the pharmacists seeing the patients for face-to-face and telephonic visits. All 4545 patients that were attributed to PAC were reviewed by student pharmacists. Although student work had to be reviewed and verified by a pharmacist, their work expedited the process and assisted in flagging patients for pharmacist review.

2.5 | Follow up monitoring

When a patient was converted from warfarin to DOAC, pharmacists educated the patient that PAC would still continue to care for them, although in a less frequent capacity compared with when they were on warfarin. Patients were instructed that PAC would reach out to them for check-in via telephone one month after the conversion. To ensure proper time was allotted to conduct the check-in call, patients were scheduled for a 15-minute phone call during a clinic visit opening. A standardized template was created to document pharmacist findings

during the call (Figure 2). The first part of the documentation was to be completed by chart review. This entailed the pharmacist reviewing laboratory results since initial conversion, medication changes, and fill history (if available). The second part of the documentation was to be completed once the patient was reached on the phone.

At conclusion of the telephone call, the pharmacist provided instruction on when to obtain repeat laboratory tests. Applicable laboratory tests orderable per consult agreement included: complete blood count (CBC), liver function tests, and renal function tests. Based on the Michigan Anticoagulation Quality Initiative (MAQI) Toolkit, CBC and liver function tests were recommended annually. Renal function was recommended annually if creatinine clearance (CrCl) was over 60 mL/min, every 6 months if CrCl was 30 to 60 mL/min, or every 3 months if CrCl was 15 to 30 mL/min.⁷ Laboratory monitoring could be ordered more frequently based on patient characteristics or pharmacist clinical judgment; patients often had these laboratory tests performed by other providers and pharmacists utilized these results if available. A follow-up phone call appointment was placed on the pharmacist schedule in 3, 6, or 12 months pending when laboratory test would be performed. Patients were also educated to call PAC if they had any changes regarding items discussed or if they were going to have an upcoming procedure. If a patient contacted PAC about an upcoming procedure, a pharmacist would review the patient chart to determine if perioperative instructions were provided to the patient.

TABLE 2 Sample script for discussing DOAC conversion

Hello Mr/Mrs XXX, I am calling from Pharmacy Anticoagulation Clinic. In light of the COVID-19 outbreak, we are looking for ways to keep our patients safe at home and decrease the need for frequent lab draws such as the INRs you have done at the clinic. I would like to see if you are interested in discussing an alternative anticoagulant that would not require routine blood monitoring.

Introduction: This is a type of anticoagulant we call a DOAC or “direct acting oral anticoagulant.” As I mentioned, the benefit is that we do not have to monitor your blood levels as frequently. Your doctor will still want to check your kidneys, liver, and/or blood counts every few months or at least yearly.

Compliance: With that said, it is imperative you do not miss doses because it is shorter acting than warfarin and one missed dose could lead to poor outcomes.

Administration: Based on discussion with patient and review of chart, DOAC chosen (often apixaban or rivaroxaban based on local formularies). The administration instructions, including instructions for missed doses, from the package insert was shared with patient.

Side effects: This is a very well tolerated medication, similar to that of warfarin in that you want to watch for signs and symptoms of bleeding or unusual bruising and contact provider immediately if that occurs.

Cost: The main barrier to using these medications can be cost. If cost is an issue, please contact the anticoagulation clinic immediately so that we can identify a solution.

Preferred pharmacy: Which pharmacy would you like me to send the prescription to?

Directions on converting: I am glad you are interested, I will also communicate the plan for this medication change with your doctor. You can check with your local pharmacy in about 1–2 days and see if they received the prescription and confirm the cost.

Pharmacists utilized package inserts to discuss conversion instructions from warfarin to DOAC. Given COVID-19 and efforts to limit face to face interaction, patients were converted based on last INR. However, if INR > 0.5 above therapeutic range or interim events, which may affect INR, Pharmacy Anticoagulation Clinic recommends patient complete lab or point-of-care INR prior to DOAC transition.

Conclude call: Please be sure to not take warfarin and DOAC together as that would put you at risk for bleeding. I want to make sure you have our phone number. You should contact us with questions, cost issues, or upcoming procedures. We will call you in 1 month to check in and see how you are doing.

Abbreviations: COVID-19, novel coronavirus disease 2019; DOAC, direct oral anticoagulant; INR, international normalized ratio.

If not, the pharmacist entered a note into the EHR outlining the type of procedure, the expected procedural bleeding risk, the patient's thrombosis risk, and recommendation for DOAC management according to institution guidance. The recommendation was sent to the provider for approval and then communicated to the patient once approved.

As of October 2020, 49 patients remained on the follow up DOAC list. This number of patients is very small in comparison to total number of patients attributed to PAC. This is further expanded upon in the next section.

2.6 | Challenges encountered

As expected, several challenges were faced during implementation of this initiative. An anticipated and significant barrier was the cost of DOAC medications compared with warfarin. The anticoagulation clinic pharmacists strived to convert a patient from warfarin to DOAC only if the pharmacist expected the patient would be able to remain on a DOAC long term. Therefore, one-time voucher cards were not routinely used. Project leads stayed attune to copayment and coverage of DOACs on different insurance plans. Ohio Medicaid has a common formulary and therefore it was expected DOACs would be covered for any patient with Medicaid insurance. Copayment cards were commonly utilized for patients with commercial insurance. The most challenging insurance was Medicare; varying plans and deductibles resulted in difficulty predicting DOAC cost.

An additional challenge, that was not expected, was patient's reluctance to transition from warfarin to DOAC. Despite DOAC education and risk/benefit discussion, pharmacists found several patients were hesitant to agree to the conversion. Patients expressed comfort with being on a medication that was closely monitored and appreciated the relationships they had built with the pharmacists. Patients also described fears of side effects to a new medication, especially during the pandemic when patients had a concern with seeking emergency care in a health system due to possible transmission of the virus. To address this challenge, ongoing education to pharmacists was provided via the frequently asked questions document discussed above. Pharmacists also encouraged patients to speak with their providers about possible conversion to DOAC if they continued to express hesitation.

Lastly, a method for long-term DOAC monitoring has proven a challenge and continues to be reevaluated. In regard to the periodic check-in calls, three main challenges have surfaced. The first being that these calls are scheduled at least 3 months into the future; patients often have forgotten about the scheduled appointment and either do not answer or are busy at the time of the call. The second challenge has been patients canceling the scheduled appointment if they do not recognize the reason it was scheduled which causes patients being lost to follow up. The third challenge has been regarding lab work. During check-in calls, pharmacists review lab work ordered at the last telephonic visit, but are finding labs done by other care team providers at different intervals than planned or that the patient has not gone to the lab to complete the lab work before the call. Due to these challenges, PAC leadership has partnered with CCHS information technology to generate real-time reports which aim to create lists of patients correctly attributed to the PAC service. Beyond review of patients on DOACs, this list is expected to be used for warfarin patient tracking and general population health efforts. In the future, pharmacy technicians may be integrated into the DOAC monitoring work flow to ensure scheduled phone visits are efficiently conducted.

2.7 | Future direction and opportunities

PAC plans for DOAC management to be incorporated into current services. There are plans to review and collect information regarding

FIGURE 2 Standardized template for DOAC follow-up documentation in EHR. CrCl, creatinine clearance; DOAC, direct oral anticoagulant

Cleveland Clinic Ambulatory Pharmacy
Anticoagulation Clinic Phone Follow-Up

Patient was contacted today to follow-up on warfarin to DOAC conversion.

Chart Review:

List DOAC, dosing	
DOAC start date	
List continued indication(s) for anticoagulation	
Adequate renal function	Yes/No
Adequate hepatic function	Yes/No
Any notable new drug-drug interactions	Yes/No
Acceptable body weight	Yes/No
Adherence (review fill dates)	Yes/No

Estimated CrCl: _____ml/min

Questions for Patient:

Have you missed any doses, and if, so how often? How did you manage your missed doses?	Yes/No
Have you had any new signs or symptoms of thrombosis?	Yes/No
Have you had any new signs or symptoms of bleeding or bruising?	Yes/No
Have you had any medication changes?	Yes/No
Have you had any issues obtaining anticoagulant refills or affording the medication?	Yes/No
Do you need refills at this time?	Yes/No
Do you have any upcoming procedures, and if so, have you been instructed on plan for managing your anticoagulant?	Yes/No
Have you had any discussions with your providers about length of therapy or plans to discontinue your anticoagulant?	Yes/No
Do you have any other concerns related to your anticoagulation?	Yes/No

Assessment/ Plan:
-Labs ordered as needed

Patient agreed to plan and reminded to contact Anticoagulation Clinic with questions/concerns. Next follow up with patient in 3 months/6 months/12 months.

Pharmacist name: _____

Pharmacy Anticoagulation Clinic
Phone:
Pager:

follow-up calls conducted during this initiative for further analysis. There is an opportunity for other institutions who pursue identification of eligible patients to collect data on patient acceptance rate and further describe findings. The ability to routinely document this information during the DOAC conversion initiative was difficult given significant and frequent changes to workflow and emergent need to implement the service during a global pandemic.

Continued education to pharmacists on this topic will be imperative to ensure ongoing competency. Leadership remains engaged with the legal department regarding feasibility of billing opportunities with telemanagement. Future discussion and planning will surround the best method to maintain DOAC monitoring. In a large academic medical center, there are several DOACs being prescribed on a daily basis. To review and manage all patients on DOACs will not be a feasible option. Further leadership discussion will surround how patients with the most need can be identified. At times, pharmacists receive

direct messages or are contacted by providers with DOAC-related questions; there has been discussion surrounding creating a formal electronic consult when providers have questions for anticoagulation pharmacists. With additional tasks being completed by the pharmacists, there will need to be a standardized way to capture work completed and time spent.

3 | CONCLUSION

PAC rose to the challenge of implementing a significant initiative in the face of a global pandemic. To continue providing the same care as pre-pandemic was not an option. Administration and pharmacy leads worked to create and modify a way to suggest warfarin to DOAC conversion in eligible patients. This initiative is likely to permanently expand the scope of practice within the pharmacist-run

anticoagulation clinics at CCHS. Other institutions could also adapt this approach as they work to expand their scope of practice in their anticoagulation clinics to include DOAC monitoring.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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